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EXAMINER

ROBERTS, PAUL A

ART UNIT PAPER NUMBER

3731

19

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/905,679

Applicant(s)

WILSON ET AL.

Examiner

Paul A Roberts

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 and 25-107 is/are pending in the application.
4a) Of the above claim(s) 8 and 83-107 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 25-34, 38, 41-53, 55, 56, 58-76 and 78-82 is/are rejected.
7) ☒ Claim(s) 35-37, 39, 40, 45, 54, 57 and 77 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 13 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 83-107 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to a method of using a surgical clip applier. The various method claims recite different a methods of using a clip applier. The device of original application could be used in alternate ways such as applying an endoluminal clip to a stomach lining. Additionally, a simple method of use of the apparatus of claim 25 would be, "The step of using the device of claim 25 to perform ligation surgery."

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 83-107 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 8 should be cancelled, as it is dependent on a cancelled claim.

Information Disclosure Statement

2. The IDS filed 12/08/03 cites references already considered by the examiner and cited in the previous Office.

Specification

3. The substitute specification was received 11/13/03. It contains many revisions as compared to the originally filed specification. These changes are not viewed as new matter

Art Unit: 3731

because the changes describe the figures more clearly and make the understanding of the disclosure easier for the reader. It is believed the applicant had possession of the concepts in the amendment at the time of filing the application, but chose not to write them at that time.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 33 and 73 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 33 recites the limitation "the nonactuable member" in line 4. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 73 recites the limitation "the jaw actuating member " in item c line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 25-29, 31-34, 38, 41-44, 46-53, 55-56, 67-76, 78-82 are rejected under 35

U.S.C. 102(b) as being anticipated by McGarry et al (McGarry) 4509518. Because the applicant

has claimed his device in some many different independent claims, multiple interpretations of McGarry were necessary to show anticipation of the above claims. Please note the part numbers may change through the rejection for different independent claims and in dependent claims where certain limitations require parts to be renamed.

8. Some general comments: the McGarry device has two strokes or stages. The first one is the stroke that forces the clip into the jaw and the second one is the stroke the closes the jaw around the clip. Additionally, the applicant never positively claims the clip. Thus the prior art must only be structurally capable of performing the below processes on the clip.

9. Regarding claim 25, McGarry discloses a clip applier with an elongate assembly (2, 3, 5 attached sheet #1) a jaw assembly (B) with 4 jaws portions (B1-B4) each leg can move towards another leg and each leg can engage a portion of a clip.

10. Regarding claim 26, a channel 8 is disclosed.

11. Regarding claim 27, the jaw is connected to the channel 8.

12. Regarding claim 28, the elongate assembly contains a jaw-actuating member (A1) movable relative to the channel (8) into contact with the jaw assembly (B) for actuating the jaw.

13. Regarding claim 29, the jaw actuating member (A1) member comprises a hollow shaft (22 of figure 5) and the channel (8) is disposed in the shaft (22).

14. Regarding claim 31, the four legs are spaced apart from one another and define a channel for the clip.

15. Regarding claim 32, A2 is a bridge member. The bridge member is deformable. The bridge member is deformable because the bridge can be bent. While, the applicant's bridge is clearly more easily deformed, the bridge of McGarry is made of metal, which is deformable.

Art Unit: 3731

Claim language like, "The bridge member acts as a leaf spring to allow both jaw parts to easily bend closer or further away" could be used to distinguish the applicant's device.

16. Regarding claim 33, element B6 is the fixed member, and the 1st and 2nd bridge member are attached to opposing sides of the fixed member. Because it is unclear what applicant means by nonactuatable member, the examiner has assumed the applicant was referring to the fixed member.

17. Regarding claim 34, the fixed member comprises a channel (8) for containing clips.

18. Regarding claim 38, the jaw contains 4 jaw cam surfaces, each on a respect jaw member. The elongate assembly comprises a jaw-actuating member (A1).

19. Regarding claim 41, McGarry discloses a clip applier with an elongate assembly containing a distal end section (7). The distal end section comprises a plurality of cam surfaces spaced around a cross-section of the distal end section. It isn't clear what the applicant means by, "The cam surfaces spaced around the cross-section of the distal end section." The examiner assumes this limitation means that the cam surfaces are proximal (nearby) the end section (and therefore the cross-section of the end section). As best understood, the cam surfaces (A1) anticipate this limitation. McGarry further discloses a jaw assembly with two jaws. McGarry also discloses an actuator assembly (figure 33) that communicates with distal end section (7) for actuating the cam surfaces into contact with the jaw assembly to cam the 1st and 2nd jaws together.

20. Regarding claim 42, the channel is element 6. It is the space between 2 and 3.

21. Regarding claim 43, the end section is movable relative to the channel.

Art Unit: 3731

22. Regarding claim 44, the shaft is element 138 of figure 31. The shaft moves the end section.
23. Regarding claim 46, the distal end section has a distal opening which can receive a clip.
24. Regarding claim 47, the jaws of McGarry has four jaw portions each of which simultaneously grab 4 portions of the clip.
25. Regarding claim 48, the 1st and 2nd legs are spaced in opposing relation, as are the 3rd and 4th legs.
26. Regarding claim 49, the elongate assembly is (2, 3, 5, & 7). The distal end is 7, clip feeding member is (2), and jaw member (A1). Two jaws are disclosed in the jaw assembly. The actuator assembly (figure 31) can create a first stage and a second stage of a first stroke. The assembly is coupled with the feeding member for moving the member into contact with the clip to feed the clip into the jaw assembly during the first stage. The assembly communicates with the jaw member to move the jaw actuator into contact with the jaw assembly to close the jaws around the clip. The feeding member remains coupled to the actuator assembly during this process.
27. Regarding claim 50, element 6 is the channel for containing clips. The feeding member and jaw member are movable relative to the channel.
28. Regarding claim 51, the jaw actuating member comprises a shaft (5), the channel is disposed within the shaft (this is true, but not shown in figure 2).
29. Regarding claim 52, the clip feeding member is disposed in the shaft.
30. Regarding claim 53, the actuator comprises a yoke. A yoke is taken to mean a part that connects at least two other parts. Yoke (the small squares in figure 3, near element 74) connects

Art Unit: 3731

72 and 78. The yoke moves the actuator when the actuator is actuated. The clip feeding member contacts the yoke and the yoke drives the member during the first and second stages.

31. Regarding claim 55, the trigger is element 18 in figure 26.

32. Regarding claim 56, the jaw actuator is element 22. The distal section urges the jaws closed. The proximal section is connected to the actuator assembly via the yoke.

33. Regarding claim 67, McGarry discloses an elongate assembly for containing an elongate assembly distal end. A jaw assembly is disclosed. A clip feeding member is disclosed. The clip feeding member contains a feeding member proximal end (92, figure 2) and an opposing feeding member distal end (112). The distal end comprises a feeder tab (102). The tab contains a concave surface for contacting a convex portion of the clip.

34. Regarding claim 68, the elongate assembly comprises a jaw actuating member (A1) which closes the jaw.

35. Regarding claim 69, the jaw actuating member comprises a shaft (22). The clip feeder is in the shaft.

36. Regarding claim 70, element 6 is the channel contained by the elongate assembly.

37. Regarding claim 71, the clip feeder is movable relative to the channel.

38. Regarding claim 72, the examiner has closely read the relevant passages about the foot member and how it is supposed to rotate the clip. However, after comparing these descriptions with the drawings, it is not clear how the foot member rotates the clip. Nonetheless, as best understood, element 24 is a foot member capable rotating the clip in the elongate assembly in response to proximal movement of the clip feeding member.

39. Regarding claim 73, McGarry discloses a clip feeding device containing an elongate assembly comprising a clip feeding member, a jaw assembly, and actuator assembly with a ratchet surface (figure 33), the actuator assembly coupled to the clip feeding member for moving the clip member in a distal direction. The actuator communicates with the jaw actuating member for moving the jaw member into engagement with the jaw assembly during a second stroke portion, and the jaw assembly allows the jaw to open. A ratchet member R2 coupled and actuatable into engagement with the ratchet surface R1 (third attached figure) during a first stroke portion is disclosed. While the handles are being compressed (the first stroke portion) the clip is prevented from moving in the proximal direction. The ratchet member is actuatable out of the engagement with the ratchet surface during the second stroke portion, which enables movement in both distal and proximal directions. The ratchet member is actuatable out of engagement with the ratchet surface during the second stroke portion for enabling movement of the jaw actuating member in both directions.

40. Regarding claim 74, the actuator contains a movable trigger (handle 18) communicating with the clip feeding member for moving the clip feeding member during the first stroke portion, and communicating with the jaw actuating member for moving the jaw actuating member during the second stroke portion.

41. Regarding claim 75, the ratchet member is connected to the trigger.

42. Regarding claim 76, the actuator comprises a movable yoke interposed between the trigger and the clip feeding member and the jaw actuating member, for translating movement of the trigger during the first stroke portion into movement of the clip feeding member, and for

Art Unit: 3731

translating movement of the trigger during the second stroke in movement of the jaw actuating member.

43. Regarding claim 78, the actuator contains a handle and the ratchet surface is disposed within the handle.

44. Regarding claim 79, the ratchet guide (R4) of the McGarry tool comprises a ratchet surface and a smooth surface (R3). The handles may be closed or opened while the ratchet is engaged to the smooth surface and only closed while the ratchet is engaged to the ratchet surface.

45. Regarding claim 80, the McGarry device discloses a clip applier comprising an elongate assembly, a distal end, a jaw assembly, a clip feeding member, an actuator, and a clip rotating member (24) disposed in the distal end.

46. Regarding claim 81, the clip rotating member extends from and is movable with the clip feeding member.

47. Regarding claim 82, the clip rotating member is positioned to contact the clip during the return stroke.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

48. Claims 30 and 58-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGarry '518 in view of Sixto Jr (Sixto) et al. 2002/0198549.

Art Unit: 3731

49. Regarding claims 30 and 58, McGarry discloses a clip applier containing: an elongate assembly having a distal end (7) and a clip feeding device 2. A jaw assembly is disclosed. An actuator assembly is disclosed, which urges the clip feeder forward, which then urges a clip into the jaw assembly. The McGarry device discloses a clip feeding stroke and a clip closing stroke, but not a clip opening stroke. However, these are method steps. The McGarry device has a defined clip feeding stroke when the handle are squeezed. Once the clip is fed, a surgeon could pull open the jaws of the tool to provide a clip opening stroke. Then the squeezing processed could be finished, and the clip closed. While the McGarry device is not intended to be used in this manner, its structure allows this usage. Nonetheless, a set of first and second hooks is not disclosed by McGarry. Sixto teaches the method of placing hooks on the end of a clip applying jaw to bend the tips of the clip. This technique is advantageous since it provides a more secure locking of the clip. At the time of the invention it would have been obvious to one having ordinary skill in the art to modify the jaw of McGarry to have hooks, and to substitute the McGarry clips with the Sixto clips into the McGarry clip channel so the McGarry device can deploy clips and bend the tips to maintain a secure connection on the tissue.

50. Regarding claim 59, McGarry discloses a clip channel.

51. Regarding claim 60, the combined McGarry device has a clip channel. The channel is capable of holding clips in a partially compressed state. While this feature is not disclosed, it is still inherent because one could force clips into the McGarry device that in the uncompressed state are larger than the clip channel, but are smaller than the clip channel in the compressed state. Again, while this may not be the method in which the McGarry device was intended to be used, the structure of McGarry renders the device capable of being used in this manner.

Art Unit: 3731

52. Regarding claim 61, the jaws can receive the clip from the elongate assembly during a slip feeding stroke. The jaw is capable of having an aperture with substantially equal to the channel width.

53. Regarding claim 62, the jaw actuating member is element A1.

54. Regarding claim 63, the actuator contains a yoke (the small square near 74, in figure 3). The yoke can be moved when the actuator is actuated. The yoke moved the clip applier toward the jaw assembly.

55. Regarding claim 64, handle 18 is the trigger.

56. Regarding claims 65 and 66, the combined McGarry device would contain 4 hooks, each on one jaw member. The jaw assembly contains 4 legs.

Allowable Subject Matter

57. Claims 35-37, 39-40, 45, 54, 57, and 77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter:

58. Regarding claims 35-37, pivot points and their structural limitations about location are not disclosed by the cited prior art in combination with the other limitations of claim 35.

59. Regarding claims 39-40, the jaw-actuating member only comprises 2 cam surfaces.

60. Regarding claim 45, the channel is not disposed between the shaft and the distal end section.

61. Regarding claim 54, the spring does not contact the clip feeding member.

Art Unit: 3731

62. Regarding claims 57 and 77, the yoke does not contain a spring.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pratt et al. 5607436 surgical clip applier


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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02/06/04


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